K040011

MAY 1 3 2004

510(k) Summary of Safety and Effectiveness Information

PRODUCT NAME

Proprietary: Polaris 2004
Common: Carbon Dioxide Gas Analyzer

ESTABLISHMENT REGISTRATION NUMBER

Establishment Registration Number: 8044004

ESTABLISHMENT ADDRESS:

Oridion Medical 1987 Ltd.
POB 45025
91450 Jerusalem Israel

CONTACT PERSON:

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Oridion Medical 1987 Ltd.
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91450 Jerusalem, Israel
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DEVICE LISTING FDA FORM 2892:

B051971

DEVICE DESCRIPTION

The Oridion Polaris Capnograph (the device being modified-K950388) is a device that measures end tidal CO_2 ($EtCO_2$). As a derivative of the $EtCO_2$ measurement the devices measure and display the breath rate (BR). The capnograph module of both devices function as a carbon dioxide gas analyzer that measures in mmHg, Vol %, or kPa the concentration of CO_2 in a gas mixture to aid in determining the patient's ventilatory status.

Substantial Equivalence Information

The modified device, the Polaris 2004 Capnograph, incorporates all the functions of the Polaris monitor. It is equivalent, in terms of indications for use and technological characteristics to the Polaris Capnograph K950388.

CLASSIFICATION Class II 73CCK

The Polaris 2004 Capnograph has been classified as follows:

21 CFR, Section 868.1400, carbon dioxide analyzer. The Capnograph device measures the concentration of carbon dioxide in a gas mixture by the use of infrared radiation as described in 868.1400. Its classification is Class II (performance standards). Since no

performance standards have been issued, it will be regulated by the Special Controls provision of the Act. The device meets the standard EN864 for capnographs that has been accepted by the FDA.

Differences Between The Polaris Capnograph and the modified Polaris 2004.

The cleared Polaris Capnograph device uses the Oridion generic CO_2 module and the modified Polaris 2004 device uses the Oridion MiniMediCO$_2$ module The Oridion MiniMediCO$_2$ CO_2 module is essentially equivalent to the CO_2 module used in the Oridion Microcap (K981114). The MiniMediCO$_2$ module takes advantage of the current availability of smaller mechanical, electrical and electronic components with lower operating power requirements. The basic design, intended use and indication of the Polaris 2004 remain the same and the design modifications have not altered the fundamental scientific technology, materials or manufacturing processes of the Polaris. The gas sampling line Filterline K980324, specified for use with this modified device, eliminates the need for a water trap. The changes pose no new issues of safety or efficacy.

Flow And Gas Sampling System

The Polaris and the modified device (Polaris 2004) use the identical flow and gas sampling system and pneumatic system. The Polaris uses plastic tubing and plastic connectors to construct the pneumatic system. The modified device uses an aluminum manifold to replace all the plastic tubing and connectors thereby reducing the size and cost and improving the reliability. The pump and solenoid used in the current device have been replaced by smaller more efficient and reliable components. The water trap used on the current device has been removed since the Oridion gas sample Filterline (K980324) accessory eliminates the need for a water trap. The removal of the water trap on Oridion capnographs has been universal (K964239, K981114, K980324, K023400) since the introduction of the Filterline CO_2 gas sampling lines (K980324, K980327, K011536, K011050).

Indications for Use:

The Polaris 2004 Capnograph is intended for the continuous, non-invasive measurement and monitoring or respiration rate and carbon dioxide concentration of the expired and inspired breath of neonatal, pediatric and adult patients wherever these measurements are required by attending medical personnel.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 3 2004

Oridion Medical 1987 Limited
C/O Mr. Sandy Brown
Regulatory Affairs Director
Oridion Capnography, Incorporated
P.O. Box 45025
91450 Jerusalem, Israel

Re: K040011
Trade/Device Name: Polaris 2004 Capnograph
Regulation Number: 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: March 11, 2004
Received: March 16, 2004

Dear Mr Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040011

Device Name: Polaris 2004 Capnograph

Indications for Use:

The Polaris 2004 Capnograph is intended for the continuous, non-invasive measurement and monitoring or respiration rate and carbon dioxide concentration of the expired and inspired breath of neonatal, pediatric and adult patients wherever these measurements are required by attending medical personnel.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040011